13.1: Introduction to preliminary studies and pilot testing

The time between the idea for an intervention trial and first entering participants into the trial is usually long, generally at least a year and often several years. Even when funding for a trial has been obtained, which, in itself, may take a year or more, there is often much work to do before the first participant can be enrolled into the trial. This chapter outlines the kinds of investigations and studies that may be carried out before starting the main trial to try to maximize the possibility that the trial will be conducted successfully. We divide these into two kinds of study. First are preliminary studies to develop different aspects of the trial procedures or to collect data to facilitate the planning and conduct of the trial. Second are pilot studies which are tests of the full trial procedures on a small sample of potential participants to make sure, in so far as is possible, that any problems with the conduct of the trial will be identified, so that procedures can be changed before the full trial starts.

Though often very useful, no specific type of preliminary study is invariably essential, whereas a pilot study should always be planned, though such studies can range from a relatively brief testing of the intervention and its evaluation that lasts a week or less through to an extensive period of testing and refinement of the intervention and evaluation methods that spans several months, or even a year or more.